FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Pulmonary-Allergy Drugs Advisory Committee (PADAC)

November 19, 20009

Draft Questions for PADAC November 19, 2009 meeting

1. Please comment on the mortality data from Spiriva HandiHaler trial 205.235 (UPLIFT).

2. Please comment on the mortality data from the Spiriva Respimat Phase 3 trials (205.244, 205.245, and 205.372).

3. Do the data from trials 205.235 (UPLIFT) and 205.266 (VA study) provide substantial and convincing evidence to support the claim that Spiriva HandiHaler reduces COPD exacerbations? (voting question)

4. Do the data from trial 205.235 (UPLIFT) adequately address the potential safety signal of stroke events? (voting question)
    If not, what additional data are needed?

5. Do the data from trial 205.235 (UPLIFT) adequately address the potential safety signal of adverse cardiovascular outcomes? (voting question)
    If not, what additional data are needed?